

### REMARKS

Claims 1-28 are pending. In response to the Office Action mailed March 12, 2008, Applicant has amended Claims 1, 2, 5, and 23. In particular, Claims 1 and 2 have been amended to clarify that the two fluid pathways allow the flow of fluid in the same direction. Additionally, Claims 1, 2 and 23 have been amended to clarify that the annular body portion of the assembly is axially moveable relative to the support ring. Claim 5 has been amended to depend from Claim 3 rather than Claim 1. Support for the amendments to the claims can be found throughout the specification and in the original claims as filed. For example, support for the amendments to Claims 1 and 2 can be found at page 12, lines 20-35 of the Specification. Support for the amendments to Claim 23 can be found, for example, in Figures 3a through Figures 5b. No new matter has been added by these amendments. Claims 1-23 are presented for examination. Reconsideration and withdrawal of the present rejections in view of the amendments and comments presented herein are respectfully requested.

Regarding 35 U.S.C. §112, second paragraph

Claim 5 was rejected under 35 U.S.C. §112, second paragraph because the limitation “second pressure differential” in line 2 had insufficient antecedent basis. Claim 5 has been amended such that it now depends from Claim 3, which recites a second pressure differential, rather than Claim 1. Applicant submits that Claim 5, as amended, fully complies with 35 U.S.C. §112, second paragraph and respectfully request that the rejection be withdrawn in view of the amendment.

The Claims, as amended, are novel under 35 U.S.C. §102 in view of Otte

Claims 1, 3-5, 8, 9, 11, 13-15, 18, 21, 25 and 26 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,468,305 to Otte (hereinafter “Otte”). Otte discloses a heart valve comprising an inner orifice ring and an outer orifice ring. These two components may be screw threaded together. Once the threads of the outer ring (32) are positioned in an unthreaded region of the inner ring, they are retained between the threads (26) of the inner ring and a retaining ridge (28). The inner ring can therefore rotate in such a configuration. Under 35 U.S.C. § 102(b), “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicant submits that

the claims are novel and not anticipated by Otte because Otte fails to teach the limitation of a second fluid pathway.

Independent Claims 1, 2, and 23 and the claims depending therefrom are directed to a heart valve assembly having a second fluid pathway defined by the annular body and the support ring. A review of the Otte reference makes clear that the second fluid pathway feature is neither taught nor suggested by Otte. Therefore, Otte cannot anticipate the claims under 35 U.S.C. §102(b). Applicant respectfully submits that because Otte does not teach each and every limitation of the claims as required by 35 U.S.C. §102(b), the claims are novel over Otte and request that the rejection be withdrawn accordingly.

Regarding Obviousness under 35 U.S.C. §103

A. Claims 2, 23, 24, 27 and 28 are patentably non-obvious over Otte in view of Sutherland

Claims 2, 23, 24, 27 and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Otte in view of U.S. Patent No. 5,401,255 to Sutherland (hereinafter "Sutherland"). According to the PTO, while Otte does not disclose an unsealed position and second fluid pathway through the assembly in response to a pressure differential, Sutherland illustrates a valve with ports that become unsealed in response to pressure to form a second fluid pathway. Thus, opines the PTO, it would have been obvious to one of ordinary skill in the art to combine the invention of Otte with the second fluid pathway of Sutherland in order to prevent backflow from the outlet to the inlet as taught by Sutherland. Applicant disagrees and submits that the PTO has failed to establish a *prima facie* case of obviousness based upon the cited references. Accordingly, Applicants request withdrawal of the rejection for the reasons set forth below.

To establish a *prima facie* case of obviousness, at least some degree of predictability is required. See MPEP 2143.02. Unpredictable results to one of ordinary skill in the art cannot support a conclusion of obviousness. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (2007). Furthermore, the subject matter of a claim is not obvious over the prior art if there is no reasonable expectation of success. *In re Rinehart*, 531 F.2d 1048, (CCPA 1976). Finally, establishing *prima facie* obviousness requires a showing that each claim element is taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580. (CCPA 1974). Specifically, establishing *prima facie* obviousness requires a showing that some combination of

objective teachings in the art and/or knowledge available to one of skill in the art would have lead that individual to arrive at the claimed invention. *See In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

In the present application, Applicant's claims are directed to a valve assembly having two distinct fluid pathways which allow the flow of fluid in the same direction. By this amendment, Claims 1, 2, and 23 have been amended to clarify that the annular body portion is axially moveable relative to the support ring. In Claims 1 and 2, it is specified that the pathways allow the flow of fluid in the same direction. The first fluid pathway is created by the opening of the moveable leaflets when they are subjected to a first pressure differential across the valve body. As the leaflets begin to open, they form (albeit briefly) an angled surface relative to the flow of the fluid. The fluid hits the angled surface and the force of fluid is momentarily sufficient to cause the annular body portion to move axially relative to the support ring. As the fluid continues to pass through the valve assembly, the annular body portion is in an unsealed position relative to the support ring, which enables rotation of the annular body portion. The resultant rotation of the leaflet members further facilitates an essentially free floating and rotating mechanism. As the pressure differential changes, the leaflets commence their movement into a second closed position and the annular body portion returns to its sealed/seated position.

The claimed valve assembly has many features and benefits which distinguish it from prior art valves. The "free floating" arrangement avoids frictional engagement between components and thus the valve has a far longer life. Further, when used in the cardiovascular system, the opening of the second fluid pathway prevents a problem which occurs in many cardiac valves, namely that blood at the edges of the vessel hit the edges of the valve assembly resulting in damage to the red blood cells. The opening of the second fluid pathway in the claimed device avoids this problem and provides a flow path for peripheral blood. Additionally, another problem faced by prior art valves is that peripheral blood or any other fluid for that matter flowing across the prior art valves form eddies at the outer edges of the valves. In the case of blood, this can be extremely problematic as reducing the flow of blood may lead to clotting. With a second fluid pathway between the body portion and the support ring, no such eddies occur and the blood is kept flowing at a rate which avoids the triggering of clotting factors.

Otte has been described *supra*. Sutherland teaches a pressure valve useful in controlling the aspiration of fluids from a patient. Side vents 72 are present in the wall of the valve to prevent a fatal increase in pressure in the heart chamber resulting from incorrect plumping of the pump components. If such a high reverse pressure is created, and the valving member fails, the reverse positive pressure is vented out via the vent ports. The side vents also allow the introduction of ambient air into the downstream region of the pump should it reach a certain negative pressure. Importantly, the valving member as disclosed in Sutherland is not axially moveable relative to a support ring but rather it is fixed in place to a wall of the assembly. This valve is quite different from the claimed valve assembly and appears to simply provide vent ports as a safety mechanism during aspiration of a ventricle in an open heart surgery procedure.

In the Supreme Court's decision in *KSR International v. Teleflex, Inc.*, the Court held that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR* at 1741 and "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* In the present case, the PTO asserts that it would have been obvious for one of ordinary skill in the art to combine the elements of Otte with the vent ports of Sutherland. However, Applicant submits that a skilled artisan would have no reason to combine these elements. Particularly, a person having ordinary skill in the art would realize that side vents in the wall of a heart valve would be entirely inappropriate.

Even if a skilled artisan was motivated to combine the teachings of Otte and Sutherland, he would not arrive at the presently claimed invention. The pump of Sutherland has side vents to enable the introduction of ambient air into the downstream region should the pressure reach a certain negative level or to vent off fluid in instances where the pressure downstream is too high. A skilled artisan would not be motivated to incorporate vents into the heart valve of Otte and there is no teaching or suggestion in Otte to do so. One need only ask where would the blood in Otte be vented?

The valve described in Otte is in a vessel and thus there is no means to vent externally such as described in Sutherland. The claims are not obvious over the Otte in view of Sutherland because there is no reasonable expectation of success in arriving at the claimed invention by

combining the reference teachings. See *In re Rinehart*, 531 F.2d 1048, (CCPA 1976). The vents of Sutherland fail to allow the flow of fluid across the valve in the same direction as the flow of fluid through the main valve opening as required in the instant amended claims and which is achieved by having the second flow path defined by the annular portion and the support ring. Thus, in light of the combined disclosures, the skilled artisan would be required to make an inventive leap to design an assembly wherein the second fluid path is defined by the inner and outer rings.

Finally, the claims of the present invention are patentably non-obvious under 35 U.S.C. §103 because the references fail to teach or suggest each and every limitation of the claims. As presently claimed, the valve assembly includes a second fluid pathway formed between the annular body portion and the support ring. By contrast, the vents in Sutherland are simply in the wall of the valve; there is clearly no second fluid pathway defined by the annular body and support ring. As discussed in detail above with reference to the § 102(b) rejection, Otte likewise lacks description or suggestion of a valve assembly having a second fluid pathway formed between the annular body portion and the support ring. Because the cited references neither teach nor suggest every claim limitation, the claims are patentably non-obvious under 35 U.S.C. §103(b) and withdrawal of the rejection is earnestly solicited.

B. Claim 10 is patentably non-obvious over Otte in view of Quijano

Claim 10 was rejected under 35 U.S.C. §103(b) as being unpatentable over Otte further in view of Quijano. Claim 10 is directed to a valve assembly as described in Claim 1, wherein at least one leaflet overlaps at least a portion of adjacent leaflet when in their first closed position. As discussed *supra*, amended Claim 1 and the claims depending therefrom include a second fluid pathway and axial movement of the annular portion of the assembly. The recitation of Quijano (U.S. Patent No. 5,500,014) fails to cure the deficiencies of Otte. While Quijano describes overlapping leaflets at Col. 9, lines 20-25, Quijano is silent with regard to a valve assembly having a second fluid pathway and axial movement of the annular portion of the valve assembly as is presently claimed in Claim 10. For at least the reasons set forth above with regard to Claim 1, Claim 10 is likewise patentably non-obvious over Otte.

C. Claim 12 is patentably non-obvious over Otte in view of Child

Claim 12 was rejected under 35 U.S.C. §103(a) as being unpatentable over Otte in view of US. Patent No. 3,835,475 to Child (hereinafter “Child”). Child discloses a silicon-alloyed Pyrolite carbon coating. According to the PTO, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Otte with the coating of Child in order to increase thromboresistance as taught by Child at Col. 2, lines 20-25. Applicant respectfully disagrees.

Claim 12 is directed to a valve assembly according to Claim 1, wherein at least one of the leaflets has a surface coating or the surface has been treated to reduce turbulence of fluid flowing past and/or over the leaflets. The Otte reference has been described in detail above with regard to Claim 1. To summarize, Applicant asserts that Otte fails to teach, suggest, or otherwise appreciate the feature of a second fluid pathway as is presently claimed. Moreover, Otte neither teaches nor suggests the axial movement of the annular portion of the valve assembly of the presently claimed invention. For the same reasons set forth above with regard to the non-obviousness of Claim 1 over Otte, Claim 12 is likewise patentably non-obvious. The disclosure of Child does not cure the deficiencies of the Otte reference in order to establish a *prima facie* case of obviousness. In particular, while Child describes a coating to increase thromboresistance, Child does not disclose a second fluid pathway as is presently claimed. Accordingly, Claim 12 is patentable under 35 U.S.C. §103(b) over Otte and Child and in condition for prompt allowance.

D. Claims 16, 17, and 20 are patentably non-obvious over Otte in view of Gorshkov

Claims 16, 17, and 20 were rejected under 35 U.S.C. §103(b) as being unpatentable over Otte in view of U.S. Patent No. 5,197,980 to Gorshkov et al. (hereinafter “Gorshkov”). According to the PTO, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Otte with the teachings of Gorshkov, namely leaflets made from pyrolytic carbon, to form valvular cusps that are biocompatible as taught by Gorshkov. Moreover, opines the PTO, it would have been obvious to substitute the support ring materials and use cobalt as taught by Gorshkov in Otte’s valve device. For at least the same reasons as set forth above with regard to Claim 1, Claims 16, 17, and 20 are patentably non-obvious in view of Otte. The addition of Gorshkov does not overcome the deficiencies of Otte to establish a *prima facie* case of obviousness. Neither Otte nor Gorshkov describe a second fluid

pathway as is presently claimed. Neither reference appreciates the advantages of a second fluid pathway nor can it be said that a skilled artisan would reasonably be motivated to combine the reference teachings to arrive at the claimed invention. While it is true that an invention may be rendered obvious by a combination of references, there must be some reasonable expectation of success derived from such a combination to render the invention obvious. Where no reasonable expectation of success is derived, Applicant submits that an obviousness rejection is improper. Furthermore, the mere fact that the teachings of Otte and Gorshkov might be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. To the contrary, absent impermissible hindsight, it would not have been obvious to combine the reference teachings and even if the references were combined, the references would still fail to teach a second fluid pathway and axial movement of the annular portion of the valve assembly, features not disclosed in either Otte or Gorshkov. For at least these reasons, Claims 16, 17, and 20 are patentably non-obvious under 35 U.S.C. §103(b) over Otte in further view of Gorshkov and withdrawal of the rejection is hereby requested.

E. Claim 19 is patentably non-obvious over Otte in view of Cohen

Claim 19 was rejected under 35 U.S.C. §103(b) as being unpatentable over Otte further in view of U.S. Patent No. 4,599,081 to Cohen (hereinafter "Cohen"). Claim 19 is directed to a valve assembly of claim 1 having the further limitation of a turbine member to optimize rotation of the annular body portion. Otte is described in detail above. In addition to not describing a second fluid pathway, Otte similarly fails to disclose a turbine member. Cohen discloses a turbine member that translates and rotates to cause occlusion or unocclusion of a valve. According to the PTO, it would have been obvious to combine the invention of Otte with a turbine member as taught by Cohen to arrive at the invention of Claim 19. Applicant disagrees.

Claim 19 depends from Claim 1. Claim 1, as detailed above, recites a valve assembly having a second fluid pathway and axial movement of the annular portion of the valve assembly. Claim 19 includes the further clarification that the valve assembly can also include a turbine member. Neither Otte nor Cohen describe valve assemblies having a second fluid pathway. The advantages of a second fluid pathway have been described above. A review of Otte reveals that a second fluid pathway was neither detailed nor contemplated as a feature of the Otte valve. Cohen does not cure the defects of Otte. While Cohen describes a turbine member for use in a

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valve, the Cohen valve suffers the same deficiencies as Otte inasmuch as a second fluid pathway is not provided. A skilled artisan in possession of the disclosures of Otte and Cohen would not be motivated to combine the references to arrive at a valve assembly having a second fluid pathway as is presently claimed for all the reasons described above. Because Claim 1, as amended, is non-obvious under 35 U.S.C. §103(b) over Otte, Claim 19 is likewise non-obvious and in condition for prompt allowance.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusions

In view of the foregoing amendment and remarks, Applicants respectfully submit that the present application is in condition for allowance. Nevertheless, the PTO is invited to contact the undersigned at the telephone number appearing below to discuss any remaining issues.



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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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